

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA

Plaintiff,

v.

B4B EARTH TEA LLC, a limited liability
company;

B4B CORP., a corporation; and

ANDREW MARTIN SINCLAIR, individually
and as an officer of B4B EARTH TEA LLC and
B4B CORP.,

Defendants.

**UNITED STATES'
OPPOSITION TO DEFENDANT
SINCLAIR'S MOTION TO
RECONSIDER AND FOR
JUDICIAL NOTICE**

Civil Action No.: 22-CV-1159

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I. INTRODUCTION

By filing his recent motion, Dkt. 55 (Def's Mot. Reconsider), Defendant Andrew Martin Sinclair ("Defendant") attempts to relitigate an argument that the Court already rejected when denying Defendant's prior motions to dismiss: that B4B Earth Tea ("Earth Tea") is a dietary supplement, not a drug. Dkts. 12, 13 (Def's Mots. to Dismiss); Dkt. 36 (Mem. & Ord. Denying Def's Mots. Dismiss). Thus, Defendant's motion, at its core, is an out-of-time motion to dismiss, and precluded by the law of the case. It is also based on a selective, and incorrect, reading of the relevant statutes.

On the basis of these arguments, Defendant also requests that the Court "dismiss" the expert report of Dr. Mariton Dos Santos, one of the United States' experts, and his motion briefly makes assertions and requests relating to both of the United States' experts that are redundant with those in Defendant's other recent motion: Dkt. 56. For the reasons provided here and in the United States' opposition to that motion, those requests by Defendant should be denied.

In sum, Defendant's motion, Dkt. 55, is without merit and should be denied.

II. DEFENDANT'S MOTION IS AN OUT-OF-TIME MOTION TO DISMISS FILED IN VIOLATION OF RULE 12, AND SHOULD BE DENIED

Civil Rule 12(b) provides: "A motion asserting any of these defenses [including failure to state a claim upon which relief can be granted] must be made before pleading if a responsive pleading is allowed." Fed. R. Civ. P. 12(b). The second form of relief Defendant's Motion requests is that the Court: "Dismiss the Plaintiff's claim that B4B Earth Tea is an unapproved new drug, as the product does not meet the legal criteria for classification as a drug under the relevant statutes." Dkt. 55 at 5. Defendant's argument is thus a purely legal one that could have been – and was – made in Defendant's failed motions to dismiss. Dkts. 12, 13. The Court set

June 7, 2022 as the deadline by which Defendant was permitted to move to dismiss any of the United States' claims. *See* April 7, 2022 Minute Order of Magistrate Judge R. Levy. That deadline has long since passed. Moreover, after the Court's denial of Defendant's motions to dismiss, Defendant filed his Answer to the Complaint on February 6, 2024, over seven months ago. Dkt. 40. For these reasons, Defendant's motion is an out of time motion to dismiss and should be rejected.

III. THE LAW OF THE CASE FORECLOSES DEFENDANT'S ATTEMPT TO RELITIGATE MATTERS THE COURT ALREADY DECIDED AGAINST HIM

The core argument in Defendant's motion, that Earth Tea is a dietary supplement, and not a drug, Dkt. 55, *passim.*, is precisely the same argument that Defendant made in his motions to dismiss years ago. Dkt. 12, 13. The Court accurately characterized Defendant's argument as a claim "that Earth Tea is a dietary supplement and therefore is exempt from regulation as a drug under the FDCA." Dkt. 36 at 4.

In the course of denying Defendant's motions to dismiss, the Court flatly rejected Defendant's argument. Dkt. 36 at 5-6 ("Succinctly, because defendant promotes Earth Tea as a treatment of cure for a disease (COVID-19), it is subject to the FDCA. . . . As a result, it is more than abundantly clear that the government has sufficiently pleaded that Earth Tea is a drug under the FDCA, and the motion to dismiss those claims must be denied.").¹ Notwithstanding the

¹ Local Civil Rule 6.3 provides that, "[u]nless provided by the court or by statute or rule . . . , a notice of motion for reconsideration must be served within 14 days after the entry of the Court's order being challenged." Lc. Civ. R. 6.3. Defendant's motion, which was served more than 9 months after the court's December 7, 2023 Memorandum & Order denying Defendant's motions to dismiss, Dkt. 36, should be denied because it fails to meet the deadline set forth in Local Rule 6.3.

Court's clearly articulated rejection of both Defendant's motion to dismiss and the faulty premise on which it was based, Defendant's instant motion repeats the same argument. Dkt. 55 at 5.²

Doubling down on his efforts to relitigate the failed argument from his motion to dismiss, Defendant relies on that argument as the sole basis for all of the relief his present motion requests, including requests that the Court: (1) "Find that B4B Earth Tea is a dietary supplement and does not meet the statutory definition of a drug under the FDCA" (an apparent request for summary judgment), (2) "Dismiss the Plaintiff's claim that B4B Earth Tea is an unapproved new drug," (3) "Dismiss the Expert Reports submitted by the Plaintiff," and (4) "Take Judicial Notice" that statutory definitions "exempt B4B Earth Tea from being classified as a drug." Dkt. 55 at 5. All of these requests should be denied under the law of the case.

While the Court is permitted to reconsider its own decisions prior to final judgment, "[t]he law of the case doctrine commands that 'when a court has ruled on an issue, that decision should generally be adhered to by that court in subsequent stages in the same case' unless 'cogent and compelling reasons militate otherwise.'" . . . [A court] may depart from the law of the case for 'cogent' or 'compelling' reasons including an intervening change in law, availability of new evidence, or 'the need to correct a clear error or prevent manifest injustice.'" *Johnson v. Holder*, 564 F.3d 95, 99-100 (2d Cir. 2009) (quoting *United States v. Quintieri*, 306 F.3d 1217, 1225, 1230 (2d Cir.2002)); accord *Pescatore v. Pan Am. World Airways, Inc.*, 97 F.3d 1, 8 (2d Cir. 1996).

Defendant's motion fails to identify any such cogent or compelling reasons; to the contrary, Defendant has put forth literally the same legal argument the Court rejected in the

² Defendant's claim in the instant motion that "[t]he mere fact that certain claims were made in marketing materials does not suffice to transform a natural dietary supplement into a drug without further factual support," Dkt. 55 at 4, ignores the Court's squarely contrary prior ruling.

course of denying Defendant's motion to dismiss: that the statutes and regulations relating to dietary supplements, not those applicable to drugs, apply to Earth Tea. Nor has Defendant presented any new evidence that would change the Court's analysis. Defendant's motion indicates that he plans to introduce and rely on a "Future Evidence Submission" consisting of "an independent scientific report" he is currently "in the process of finalizing," but Defendant has not actually provided that report to the Plaintiff or the Court. Dkt. 55 at 4–5. Moreover, any new study of Earth Tea's efficacy that Defendant may presently be conducting is irrelevant to the United States' claims in this case, which allege that Earth Tea was an unapproved new drug *at the time Defendant distributed it* and that Defendant lacked sufficient scientific evidence to substantiate his health-related marketing claims *at the time he made them*. Thus, based on Defendant's description of his forthcoming report, it is apparent that it will have *no effect* on the Court's analysis of whether Defendant violated the Federal Food, Drug, and Cosmetic Act, the Federal Trade Commission Act, or the COVID-19 Consumer Protection Act.

IV. DEFENDANT'S PURPORTED BASIS FOR HIS CLAIM IS INCORRECT

Throughout his motion, Defendant claims that 21 U.S.C. § 343(r)(6) exempts dietary supplements from being classified as drugs:

B4B Earth Tea is a natural dietary supplement and falls under specific exemptions provided by 21 U.S.C. § **343(r)(6)**. . . . B4B Earth Tea has been consistently marketed as a natural dietary supplement, a product category that is exempt from drug classification under 21 U.S.C. § **343(r)(6)**, provided that any labeling or claims made are truthful and not misleading. . . . This Court should take mandatory judicial notice of the statutory definition of the term 'drug' under 21 U.S.C. § 321(g)(1) and the related statutes that exempt dietary supplements from being classified as drugs under 21 U.S.C. **343(r)(6)**.

Dkt. 55 at 1-3, 5 (emphasis added).

However, the black-letter language of Section 343(r)(6) states plainly that claims of efficacy against specific diseases are prohibited: "A statement under this subparagraph may not

claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.” 21 U.S.C. § 343(r)(6).

As noted by the Court, this case alleges that “Sinclair represented that Earth Tea is a ‘proven natural treatment for COVID-19’ that is more effective than the available vaccines. It is of no help to him that he refers to Earth Tea as a ‘Natural Supplement Drink’ in his motion.” Dkt. 36 at 5. The alleged marketing representations are not in dispute; Defendant admits them in his present motion, Dkt. 55 at 2 (“Defendant acknowledges the marketing statements made on social media platforms but contends that these statements were neither misleading or false.”³), and he also admitted them at his deposition.

Indeed, at his deposition, Defendant testified that he made numerous statements that Earth Tea is effective against COVID-19 and other diseases, including cancer, as well as prostate issues that would otherwise require surgery. Ex. 1 (Excerpts of Defendant’s 5/30/2024 Deposition) at Tr. 76:14-77:20 (“EARTH TEA PROVEN TREATMENT FOR COVID-19. WORKS WITHIN MINUTES. GET OUT OF QUARANTINE WITHIN 24HRS. GUARANTEED.”); at 81:8-18 (“To this day.. Earth Tea is the most effective Treatment against#COVID 19 as Treatment and Prevention”); at 118:23-119:22 (“If your plan is to go Unvaccinated here’s a must have natural immune booster. Earth Tea Extra Strength, it works extremely fast and it’s 100% effective against Covid19.”); at 135:15-136:7 (“If you’re battling cancer, B4B Earth Tea can help save you.”); at Tr. 171:24-172:24 (“4 [bottles of Earth Tea] is

³ Contrary to Defendant’s suggestion, the truthfulness of a labeling claim is irrelevant to whether a product is a drug, and it does not make a product “exempt from drug classification.” Dkt. 55 at 2. In any event, Defendant’s claims are misleading because he lacked sufficient scientific substantiation for them.

enough to get rid of cancer.”); and at Tr. 139:11-23 (“If you’re scheduled for prostate surgery...we can help you avoid surgery.”).

The cases cited by Defendant are irrelevant. In *United States v. Article of Drug Ova II*, the Court held that a pregnancy test was not a drug because pregnancy is not a disease. 414 F. Supp. 660, 664-66 (D.N.J. 1975). This result has no bearing on this case, in which Defendant has made dozens of claims that his product is effective against COVID-19 and other diseases.

Similarly, while Defendant claims that *Whitaker v. Thompson* “ruled that structure/function claims made about dietary supplements are protected under 21 U.S.C. § 343(r)(6) and cannot be classified as ‘Drugs,’” Dkt. 55 at 4, this assertion is both inaccurate and inapplicable to this case. The *Whitaker* court stated that, if a claim is made in accord with Section 343(r)(5)(D) “as well as other sections of the statute,” the claim is not subject to the requirements applicable to drugs. *Whitaker*, 248 F. Supp. 2d 1, 3 (D.D.C. 2002). As noted previously, the “other sections of the statute” include Section 343(r)(6), which expressly prohibits disease claims. 21 U.S.C. § 343(r)(6). As Defendant acknowledges, Dkt. 55 at 4, the claim at issue in *Whitaker* was a “structure/function” claim, and not a claim that the product was an effective cure, prevention, or treatment for a particular disease, such as the numerous claims Defendant has made that Earth Tea is effective against COVID-19 and other diseases. Thus, *Whitaker* is of no help to Defendant.

Consequently, even if Defendant’s motion had not been an out-of-time motion to dismiss that is foreclosed by the law of the case, it should nonetheless be rejected because, at its core, it is based on a selective and incorrect reading of federal statutes that fails to support Defendant’s arguments.

V. THE RELIEF REQUESTED IN DEFENDANT’S MOTION SHOULD ALSO BE DENIED FOR THE REASONS PROVIDED IN THE UNITED STATES’ OPPOSITION TO DEFENDANTS’ OTHER RECENT MOTION

Defendant’s motion includes a request that the Court dismiss the expert reports of the United States two experts. Dkt. 55 at 5. Defendant concurrently filed another motion, Dkt. 56, making the same request. That request should be denied for the reasons described above and the reasons provided in the United States’ opposition to Defendant’s motion at Dkt. 56, which are incorporated herein by reference.

CONCLUSION

For the reasons provided above, Defendant’s motion is meritless and should be denied.

Dated: October 1, 2024

Respectfully submitted,

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